



**Indiana State  
Department of Health**  
*An Equal Opportunity Employer*

**Mitchell E. Daniels, Jr.**  
*Governor*

**Judith A. Monroe, M.D.**  
*State Health Commissioner*

**DATE:** August 21, 2009

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** A. Scott Gilliam, MBA, CP-FS  
Manager, Food Protection Program

**SUBJECT:** Qualitest Pharmaceuticals Inc Recall

**SUGGESTED**

**ACTION:** Unclassified Recall; Accusure® Insulin Syringes (1/2 cc – 31 G – Short Needle) with lot number 6JCB1 (Expiration 10/2011) – NDC 0603-7001-21 and Accusure® Insulin Syringes (1 Cc – 31 G – Short Needle) Lot #7cpt1; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. When the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after an injection. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

\*\*\*\*\*

**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

**Qualitest Pharmaceuticals, Inc.**  
**Issues a Voluntary Nationwide Recall of**  
**Accusure® Insulin Syringes (1/2 Cc – 31 G – Short Needle) Lot #6jcb1**  
**and Accusure® Insulin Syringes (1 Cc – 31 G – Short Needle) Lot #7cpt1**

**Contact:**  
Qualitest Pharmaceuticals  
Larry Kass  
1 (800) 444-4011

2 North Meridian Street • Indianapolis, IN 46204  
317.233.1325 tdd 317.233.5577  
[www.statehealth.in.gov](http://www.statehealth.in.gov)

The Indiana State Department of Health supports Indiana's economic prosperity and quality of life by promoting, protecting and providing for the health of Hoosiers in their communities.

**FOR IMMEDIATE RELEASE** -- August 21, 2009 -- Huntsville, AL - Qualitest Pharmaceuticals, Inc., today has issued a voluntary nationwide recall of Accusure® Insulin Syringes (1/2 cc – 31 G – Short Needle) with lot number 6JCB1 (Expiration 10/2011) – NDC 0603-7001-21. This lot was distributed between January 2007 and June 2007 to wholesalers and retail pharmacies nationwide (including Puerto Rico). Also today, Qualitest has issued a voluntary nationwide recall of Accusure® Insulin Syringes (1 cc – 31 G – Short Needle) with lot number 7CPT1 (Expiration 03/2012) – NDC 0603-7002-21. This lot was distributed between May 2007 and June 2008 to wholesalers and retail pharmacies nationwide (including Puerto Rico). The syringes in these lots have been found to have needles which can detach from the syringe.

When the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after an injection.

Consumers who have any Accusure® Insulin Syringes (1/2 cc – 31 G – Short Needle) with lot number 6JCB1 or Accusure® Insulin Syringes (1 cc – 31 G – Short Needle) with lot number 7CPT1 should stop using them and contact Qualitest at 1-800-444-4011 for product replacement instructions. You can find the lot number on the white paper backing of each individual syringe.

Qualitest is notifying all customers who received the product and arranging for return of any affected product.

This recall is being made with the knowledge of the Food and Drug Administration.

Consumers with questions may contact Qualitest at 1-800-444-4011 for more information.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- **Regular Mail:** use postage-paid FDA form 3500 available at: [www.fed.gov/MedWatch/getforms.htm](http://www.fed.gov/MedWatch/getforms.htm)  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-FDA-0178

###